



Drexel Research Agent Exception Form and Investigator Agreement

In exceptional circumstances, individuals who do not meet the eligibility requirements outlined in “ORI-004 - Drexel Research Agent Eligibility and Responsibilities” may serve as a Drexel Research Agent by requesting an exception and completing an Investigator Agreement. This form must be completed on an individual project basis and certified by the proposed agent and project PI, as evaluated and permitted by the Institutional Official, who may consult with relevant offices. In the case of research that requires oversight by the IACUC or IRB, these will have final authority to approve an individual as a Drexel Research Agent per the regulatory requirements to ensure appropriate oversight and responsibilities and may have additional submission requirements. Additional materials may be required per the applicable office (e.g., CV/resume for IRB review).

The Exception Form and Investigator Agreement should be prepared and attached to applicable submissions. Please note that an approved exception for one project does not guarantee approval of future exceptions for an individual.

General Information

Name of Proposed Drexel Research Agent:

Current Affiliation/Status (e.g., Part-Time Faculty):

Department/School/Institute Name:

Study Title:

Project PI:

Is this project sponsored?

If Yes,

Who is the sponsor?

What is the start date of the award?

What is the end date of the award?

IACUC#:

IRB#:

Proposal#:

Brief description of the work performed at Drexel:

Study Specific Justification Reasoning

- 1) Please explain/justification/reason why this exception is needed:

- 2) Please provide how the Research Agent's research experience, expertise, and training lends itself to the proposed project:

- 3) If the Research Agent is faculty, staff, agent, or otherwise employed by another entity, institution, or organization, please provide the details of this engagement, why you are requesting to conduct this work at Drexel, and if this other entity, institution, or organization has provided permission to proceed:

- 4) Has the Research Agent ever received a 483 (FDA), been sanctioned or debarred by an institution, regulatory agency, or funder, or had research personnel privileges suspended or terminated? If no, please state N/A, otherwise please provide additional information (e.g., timeline, resolution, institution):

- 5) Has the Research Agent received a Serious or Continuing Noncompliance determination in the last three years? If no, please state N/A, otherwise please provide additional information (e.g., timeline, resolution, institution):

Proposed Drexel Research Agent:

My signature below indicates the following:

- 1) The information above is true and accurate to the best of my ability. Failure to provide true and accurate information can lead to immediate suspension of research privileges, impact my employment or engagement with Drexel University, and be reported as required to regulatory agencies.

- 2) I have reviewed all documents associated with the project/proposal and understand that if approved, I am acting as a Research Agent of Drexel University under the purview of Drexel University's Institutional Official and the Project's Principal Investigator.
- 3) I understand it is my responsibility to be aware of and abide by all applicable regulations and requirements governing my specific project/proposal.
- 4) I understand it is my responsibility to be aware of and abide by Drexel University's policies, procedures, and guidelines, as well as institutional and research requirements.
- 5) I understand that any data or materials associated with this project are considered Drexel University property and cannot leave the institution unless permitted by an appropriately executed MTA or DUA.
- 6) I will complete and maintain all Drexel University required training for the duration of this project.
- 7) If my information above changes (e.g., licensure expiration, suspension of privileges), I will notify my project PI and Drexel University's Office of Research & Innovation immediately, no later than five calendar days.
- 8) I confirm that my collaboration on the above referenced research project is independent of any other organization or institution as I am:
 - (a) not otherwise an employee or agent of an assured (i.e., FWA holding) institution, and
 - (b) not acting as an employee of any organization or institution with respect to my involvement in the research being conducted at Drexel University, and
 - (c) not using the collaboration for scholarly advancement (e.g., promotion, tenure) at an organization or institution, or
 - (d) not engaging any other institutions that I am affiliated with in human subjects research.

Proposed Drexel Research Agent Signature

Date

Principal Investigator:

My signature below indicates the following:

- 1) The information above is true and accurate to the best of my ability. Failure to provide true and accurate information can lead to immediate suspension of PI privileges, impact my employment with Drexel University, and reported as required to regulatory agencies.
- 2) I understand that I am ultimately responsible for the conduct of this research.
- 3) The proposed Drexel Research Agent has the necessary experience, expertise, licensures, and credentials to conduct this proposal/project.
- 4) As the PI, I will ensure that the proposed Drexel Research Agent has completed all institutional requirements to conduct the proposed research prior to the initiation of activities.
- 5) If I am made aware of any of the proposed Research Agent's information changing (e.g., licensure expiration, suspension of research privileges), I will notify Drexel University's Office of Research & Innovation immediately, no later than five calendar days.

PI Signature

Date